K023485

DEC 0 2 2002

510(k) SUMMARY

Submitter's Name: EVERMED Corporation
4999 E. La Palma Avenue
Anaheim, CA 92807
(714) 777-9997

Date summary prepared: October 16, 2002

Device name:

Proprietary name:	Explorer™ Powered Wheelchair
Common or usual name:	Power chair.
Classification name:	Powered wheelchair, Class II, 21 CFR 890.3860.

Legally marketed device for substantial equivalence comparison:

Regency Power Wheelchair submitted by Gendron, Inc. and cleared for marketing under 510(k) #K001923.

Description of the device:

The Explorer™ Powered Wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The product has a metal frame with four wheels, an adjustable seat with armrests, and a controller attached to one armrest. The controller allows the rider to control the movement of the chair. The chair can be disassembled for transport and is provided with a battery charger.

Intended use of device:

The EVERMED Explorer™ Powered Wheelchair provides enhanced mobility to physically challenged persons limited to a sitting position.

Technological characteristics:

The device features and use parameters of the Explorer™ Powered Wheelchair and the Regency Power Wheelchair are very similar. Both have tubular metal frames, are battery operated, have two motors, and have automatic braking systems. Both use the same controller. Battery chargers and instructions for their use are supplied with both chairs. Use parameters are very similar as well, with minor variations in such areas as travel range and maximum speed.

Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles,* July 1995, were conducted and the results included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 2 2002

Evermed Corporation
R.S. McQuate & Associates, Inc.
c/o Robert S. McQuate
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K023485
Trade/Device Name: Explorer™ Powered Wheelchair
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 16, 2002
Received: October 17, 2002

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K023485

Device name: Explorer™ Powered Wheelchair

Indications for Use: The Explorer™ Powered Wheelchair provides enhanced mobility to physically challenged persons limited to a sitting position.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

Miriam C. Provost

K023485